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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/994,412

11/27/2001

Ulrich Certa

20787

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7590

03/23/2006

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,412

Applicant(s)

CERTA ET AL.

Examiner

Kimberly Chong

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 01/09/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 09/07/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 01/09/2006, claims 1-6 are pending in the application.

Applicant's arguments are moot in view of the amendments filed 01/09/2006 and the new grounds of rejections below.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in EPO on 11/29/2000. It is noted, however, that applicant has not filed a certified copy of the EPO 00126113.0 application as required by 35 U.S.C. 119(b). As such, Applicant cannot rely upon the foreign priority papers to overcome the rejection under 35 U.S.C. 102(b) as being anticipated by Heifetz et al., as per below, because a certified copy of the EPO 00126113.0 application has not been made of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Heifetz et al. (WO 00/68374 cited on PTO-form 1449 filed 03/18/2005).

The instant claims are drawn to a process for inhibiting expression of a target gene in cells or tissues comprising infecting said cells or tissue with a first set of viral particles expressing a sense RNA strand and a second set of viral particles expressing an antisense RNA strand, wherein the sense and antisense RNA strands comprise homologous nucleotide sequences to a portion of said target gene, wherein said cells or tissues are infected with equal amounts of viral particles consisting of sense ssRNA and viral particles consisting of an antisense ssRNA, wherein the target gene is eukaryotic, viral or synthetic and the homologous nucleotide sequence is at least 50 bases in length and is specific for a target gene.

Heifetz et al. teach a process for inhibiting expression of a gene in a plant cell by administration of a sense ssRNA fragment and an antisense ssRNA fragment wherein said sense RNA fragment and said antisense RNA fragment are capable of forming a double-stranded RNA molecule (see page 7). Heifetz et al. teach viral vectors for introduction of said RNA fragments into plant cells (see page 11). Heifetz et al. further teach the target gene is a plant developmental gene or a plant enzyme (see page 5) and the ribonucleic acid sequences are preferable at least 50 bases in length (see page 11).

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Thus, Heifetz et al. anticipates claims 1 and 4-6 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heifetz (cited on Form PTO-1449 filed 3/18/02) in view of Lundstrom K. (cited on Form PTO-892 filed 09/7/05).

The instant claims are drawn to a process for inhibiting expression of a target gene in cells or tissues comprising infecting said cells or tissue with a first set of viral particles expressing a sense RNA strand and a second set of viral particles expressing an antisense RNA strand, wherein the sense and antisense RNA strands comprise homologous nucleotide sequences to a portion of said target gene, wherein the virus is an alphavirus, wherein the target gene is eukaryotic, viral or synthetic and the homologous nucleotide sequence is at least 50 bases in length and is specific for a target gene.

Heifetz et al. teach a process for inhibiting expression of a gene in a plant cell by administration of a sense ssRNA fragment and an antisense ssRNA fragment wherein said sense RNA fragment and said antisense RNA fragment are capable of forming a double-stranded RNA molecule (see page 7). Heifetz et al. teach viral vectors are used to introduce said RNA

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fragments into the plant cells (see page 11). Heifetz et al. further teach the target gene is a plant developmental gene or a plant enzyme (see page 5) and the ribonucleic acid sequences are preferable at least 50 bases in length (see page 11). Heifetz et al. does not teach the viral vector is an alphavirus.

Lundstrom teach alphavirus vectors, such as Semliki Forest Virus vectors, for production of high titer viral particles (see page 680).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an alphavirus vector, as taught by Lundstrom, to deliver the RNA to plant cells, as taught by Heifetz et al.

One would have been motivated to use alphavirus vector because Lundstrom specifically teach alphavirus are known for their extremely broad host range and therefore capable of infecting numerous cell types (see page 680). Lundstrom teach alphavirus vectors are easy to produce and have the ability to produce high titer viral particles that make them favorable for gene therapy applications (see page 680).

Finally, one would have a reasonable expectation of success because Lundstrom teach production of alphavirus particles and use in gene transfer into cells. Further Lundstrom teach an efficient high titer alphavirus viral particle packaging system.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-2 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heifetz (cited on Form PTO-1449 filed 3/18/02).

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The instant claims are drawn to a process for inhibiting expression of a target gene in cells or tissues comprising infecting said cells or tissue with a first set of viral particles expressing a sense RNA strand and a second set of viral particles expressing an antisense RNA strand, wherein the sense and antisense RNA strands comprise homologous nucleotide sequences to a portion of said target gene, wherein the target gene is eukaryotic, viral or synthetic and the homologous nucleotide sequence is at least 50 bases in length and is specific for a target gene.

Heifetz et al. teach a process for inhibiting expression of a gene in a plant cell by administration of a sense ssRNA fragment and an antisense ssRNA fragment wherein said sense RNA fragment and said antisense RNA fragment are capable of forming a double-stranded RNA molecule (see page 7). Heifetz et al. teach viral vectors for introduction of said RNA fragments into plant cells (see page 11). Heifetz et al. further teach the target gene is a plant developmental gene or a plant enzyme (see page 5) and the ribonucleic acid sequences are preferable at least 50 bases in length (see page 11). Heifetz et al. does not teach infection of cells with equal amounts of a viral particle consisting of a RNA sense RNA and a viral particle consisting of a RNA antisense RNA.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to infect cells with equal volumes of viral particles for the purposes of forming a dsRNA molecule. One of skill in the art would have motivated to use equal volumes of a viral particle comprising a sense RNA and a viral particle comprising an antisense RNA to allow efficient formation of dsRNA molecules for the purposes of interfering with gene expression.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Applicant's Arguments

Claim Rejections - 35 USC § 112

The rejection of record of claims 1-6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in response to Applicant's amendments filed 01/09/2006.

Claim Rejections - 35 USC § 102

The rejection of record of claims 1, 2, 4 and 6 under 35 U.S.C. 102(b) as being anticipated by Ding et al. (Nucleic Acids Research, 1998) is withdrawn.

Claim Rejections - 35 USC § 103

The rejection of record of claims 1-4, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (Nucleic Acids Research, 1998) in view of Fire et al. (see form PTO-892, US Patent Documents #A) is withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

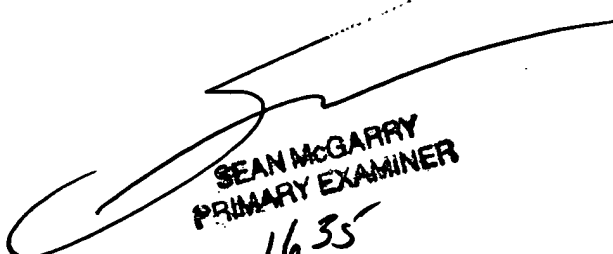
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635


SEAN MCGARRY
PRIMARY EXAMINER
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